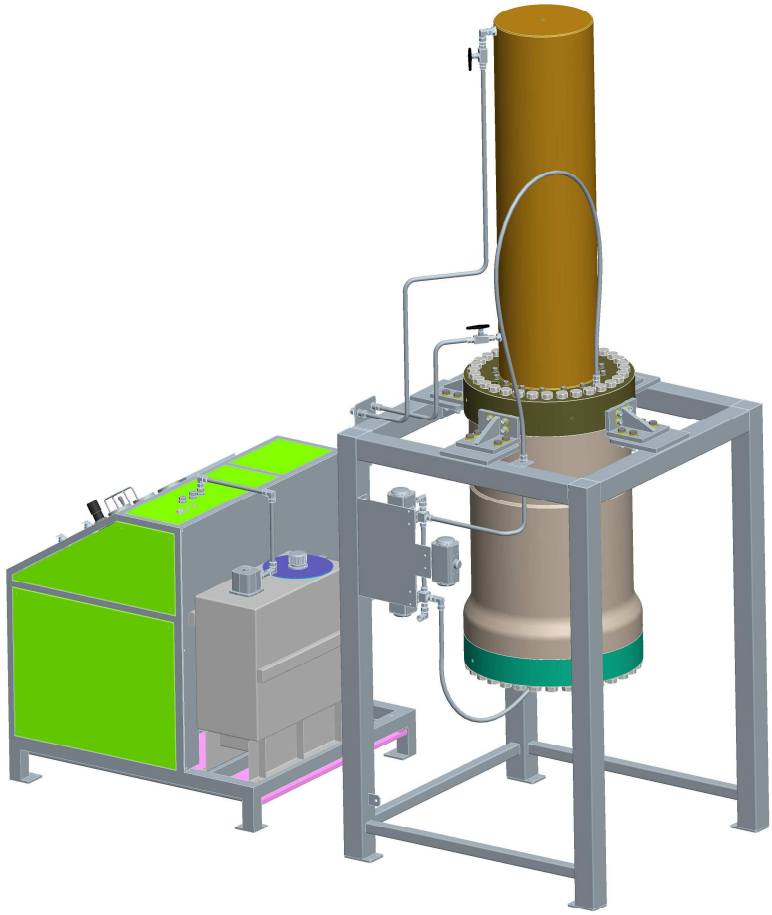
Process

Novasep

novasep process



LC590.700.VE100

NVS22701

Pure Performance for the Life Sciences

TECHNICAL & PROCESS DESCRIPTION : Dec. 2010

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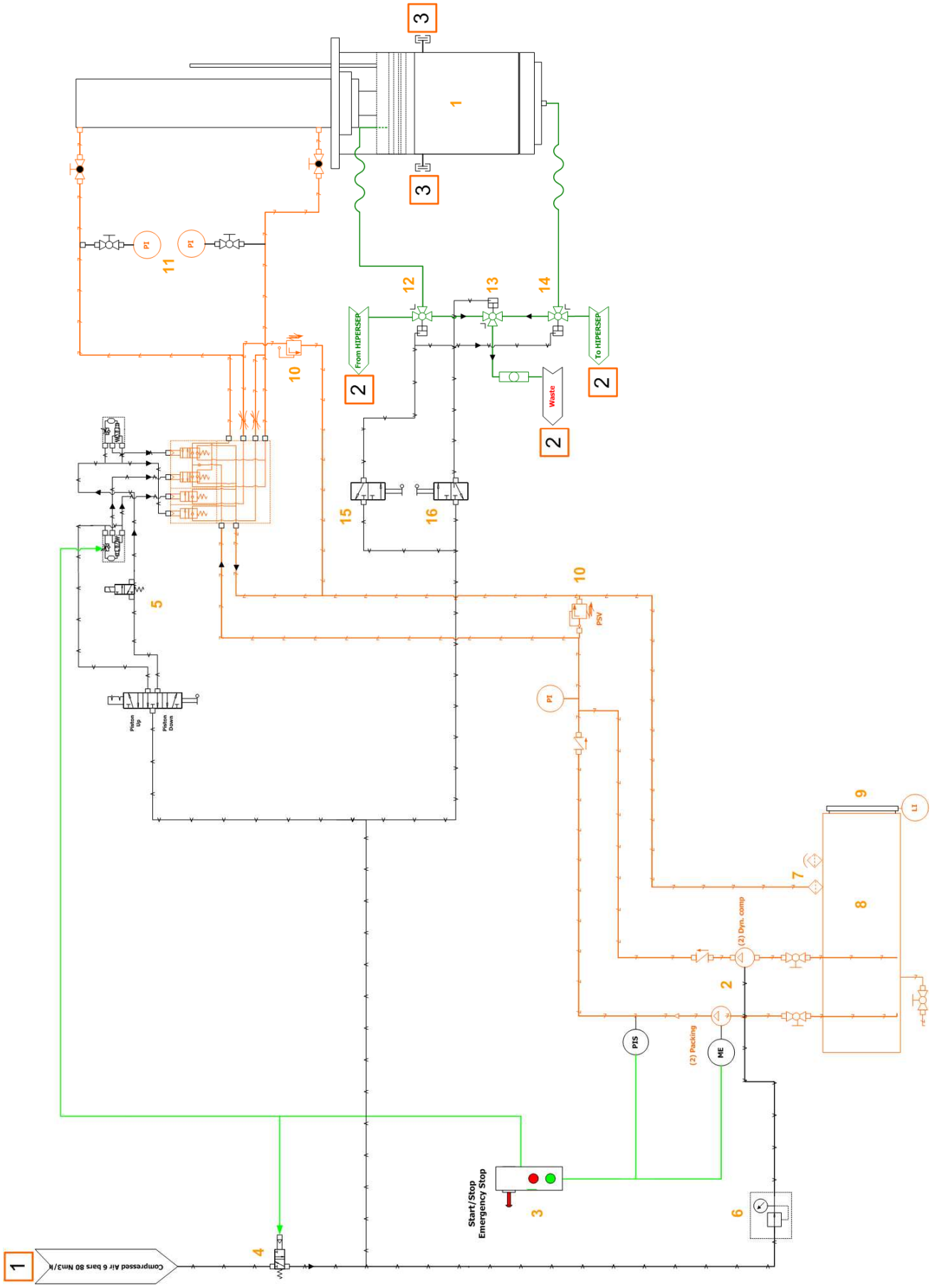
1. TECHNICAL DESCRIPTION

1.1. FLOW CHART



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1.2. TECHNICAL SUMMARY

The **LC590.700.VE100** preparative High Performance Liquid Chromatography (HPLC) column is designed for cGMP operation. Any type of packing material can be used to fill the column provided the proper packing pressure is chosen to avoid destruction of the particles. It can be operated with the most common solvents used in chromatography. The column module is composed of the column itself and its compression system mounted on a stainless steel frame. It can be connected to any pumping system.

MAIN CHARACTERISTICS			
Internal Diameter	590 mm	**Operating Temperature**	5 to 60°C
Maximum Bed Length	400 mm	**Compression feature**	Dynamic Axial Compression (DAC)
Operating pressure	100 bar	**Slurry inlets**	1

LC590.700.VE100	
ITEM	**DESCRIPTION**
Column (1)	**Column Tube** The internal diameter of the column tube is 590 mm. The standard surface roughness of the column tube ID is 0.4 µm (15.7 µ inches). The external finish is approximately 1.6 µm (63 µ inches). **Piston and Flange** The piston and flange of the column contain a woven mesh frit (2µm nominal porosity) and a flow distributor to provide even distribution of the liquid (”plug flow”) over the cross section of the packed bed. The finish of the wetted surface roughness of the piston and flange is approximately 0.8µm (30 µ inches) The flange is sealed to the column tube with a FEP encapsulated "O"-ring and held in place by the use of screws. The piston is sealed to the column tube with a dynamic spring-loaded seal. The piston seals are PTFE, FEP encapsulated and SS316L. **Hydraulic Jack** The hydraulic jack is mounted above the column tube. The hydraulic jack has a stroke length of 700 mm, which allows the user to pack beds of variable lengths. The hydraulic jack exterior is painted steel (Novasep standard paint).
Hydraulic pumps (2)	An electrical driven pump is used to motion the piston up and downwards. An air driven amplification pump is used to pressurize the oil and to maintain the dynamic axial compression onto the packing material. The oil pressure is proportional to the air supply pressure in static conditions (piston not moving).
Emergency Stop Reset button (3)	Emergency stop to shut down the hydraulic pump in case of emergency. Pneumatic push button to reset the hydraulic unit after the emergency button has been disengaged
Air supply Valve (4)	Pneumatic 2 way valve, used to supply the hydraulic pump with compressed air.
Motion Selector Oil distributor (5)	Pneumatic switch to control the oil distributor in order to select the piston’s motion (up, down, stop).
Pressure Regulator (6)	Air pressure regulator to set the air pressure supply to the pneumatic amplification pump (N^2). The air pressure is linear with the oil pressure.
Filter (7)	Breather filter for the oil reservoir
Filter (7’)	Oil return filter for mounted on the oil reservoir
Oil reservoir (8)	Reservoir for the hydraulic oil with 90L capacity.
Level indicator (9)	Oil level indicator for the oil reservoir.
Relief valve (10)	Oil pressure relief valve to protect the column in case of an accidental over-pressure. This relief valve can be : ● **CODAP** certified for EU version ● **ASME** Certifed for US version
Pressure gauge (11)	Pressure gauge indicating the oil pressure. This indication is used to determine the bed compression.
Packing valves (12, 13, 14)	Pneumatic 3-way ball valve to isolate the column from the pumping skid for the packing and unpacking operations and to select solvent direction toward the flange’s or piston’s side during packing operation in order to bleed the air and/or remove the slurry solvent.
Column state Selector (15’)	Pneumatic switch to change the column state from elution mode to packing mode by actuating packing valves.
Purge state Selector (16’)	Pneumatic switch to change the purge state during packing operation from piston to flange by actuating the packing valve.

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ITEM	DESCRIPTION
Jack isolation valves (17 & 18)	Manual 2-way ball valve to isolate the jack for maintenance purposes.
Sight glass (19)	Sigth glass installed on the purge line to identify liquid or air presence during packing operation.
Pressure transmitter (20)	Optional pressure transmitter and its isolation valve. The pressure transmitter can be connected to the HIPERSEP unit in order to manage (record & alarm) the hydraulic oil pressure.

LC590.700.VE100

Option

The design of the Column is made in such a way to reduce as much dead volume as possible. All wetted parts of the column module are made of SS316L stainless steel, FEP and PTFE.

Packing valves are high pressure valves with an internal surface finish not better than 2.4 µm (94 µ-inches).

Frame is made of SS304 with an external finish at Grit 220 (about 1.6 µm Ra / 62 µ-inches Ra). External frame's welds are grinded.

The LC590.700.VE100 is rated to be operated in ATEX Zone 2 IIB T4 hazardous area (refer to section 2).

1.3. DYNAMIC AXIAL COMPRESSION

The Column Skid is a self packing column. It is based on the Dynamic Axial Compression (DAC) technology. Its main feature is the presence of a piston attached to a hydraulic jack. The piston travels the entire length of the column tube. The hydraulic jack is operated by the Hydraulic Unit. The piston has three functions in the DAC column:

Column Packing

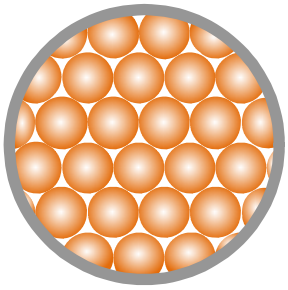
A slurry of packing material in an appropriate solvent, is first transferred into the column tube through 1 side fill nozzle. The piston is then moved downward thus eliminating :

- firstly the air through the frit of the column piston,
- secondly the slurry solvent through the frit of the column flange.

When the packing process is complete, the piston stops moving. The column is then ready for use. The whole packing process typically takes less than 20 minutes, including the slurry preparation.

Maintaining Bed Stability

During the column operation, the particles of packing material reorganize over the time and the whole bed tends to settle, usually forming a void at the fixed bed column inlet with a concomitant decrease in column performance. The dynamic action of the piston provides **continuous compression** to the bed and prevents void formations, thus providing a stable column performance over the time.



Good packing bed arrangement

Column Unpacking

In order to unpack the column, the pressure is released from the hydraulic system and the column flange is removed. An appropriate sized container is placed under the column tube. The hydraulic pressure is then increased and the piston is directed downward to push the packing material out of the column and into the container. The unpacking time is less than 30 minutes.

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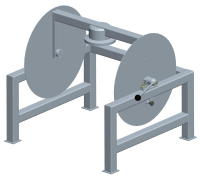
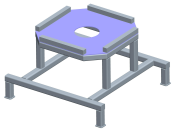
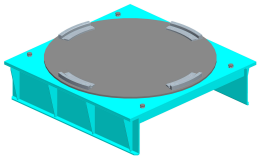
1.4. HANDLING TOOLS

These accessories, mainly made of SS304L stainless steel, are used to simplify the piston and flange removal/ installation procedure. They include a manual forklift , a piston rotation unit, a piston table and a flange table.

The table frame is placed under the column using the manual forklift. The table is lifted up until it comes in contact with the piston (which has been previously set to its lowest position) or the flange. For the piston, the special quick release chain attaching the piston to the jack is then opened and the piston sits free on the table. Finally, the table is lowered, with the piston or the flange on top of it, and can be pulled away. If desired, the piston can then be attached to the piston rotation unit where it can easily be rotated (to clean/change the frit or the seals).

The reversed procedure is used to install the piston or the flange.

LC590.700.VE100 HANDLING TOOLS		
TYPE	**DESCRIPTION**	
Manual forklift	This manual forklift has 2 main functions: • Install and remove the piston onto/from the column • Install and remove the flange onto/from the column The manual forklift mainly is made of SS304. The forklift and all its components (including wheels) are **compliant** with **ATEX** (no aluminum used in the construction).	
Piston Rotation Unit	This accessory is used to remove the piston from the Piston table and rotate it for maintenance operations (cleaning/changing piston frit and seals). The rotating section is designed in such a way that minimum effort is required to rotate the piston. This accessory is mainly made of SS304.	
Piston/Flange tables	These tables are used to accommodate the piston and flange once they are removed from the column. These accessories are mainly made of SS304.	 

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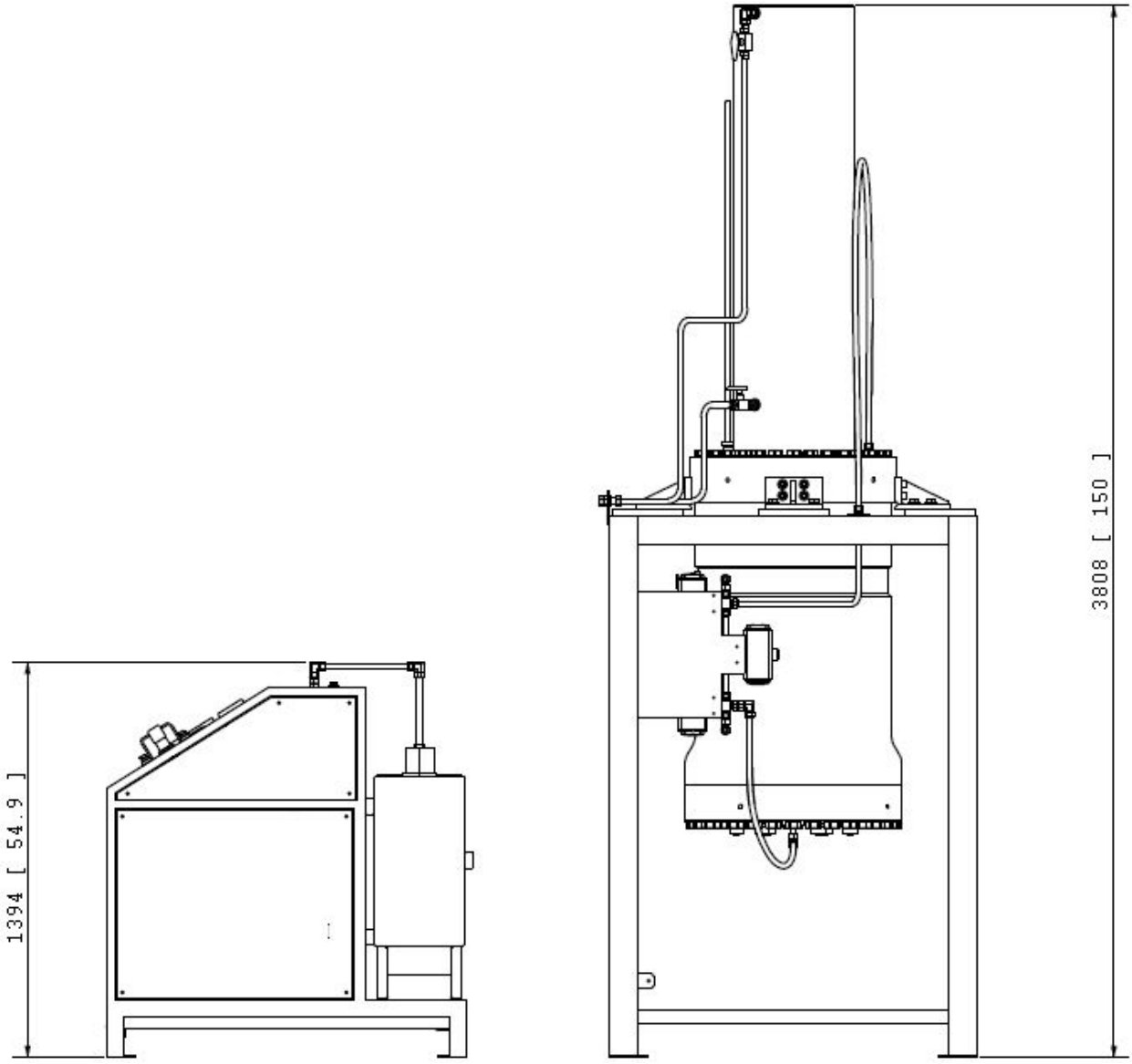
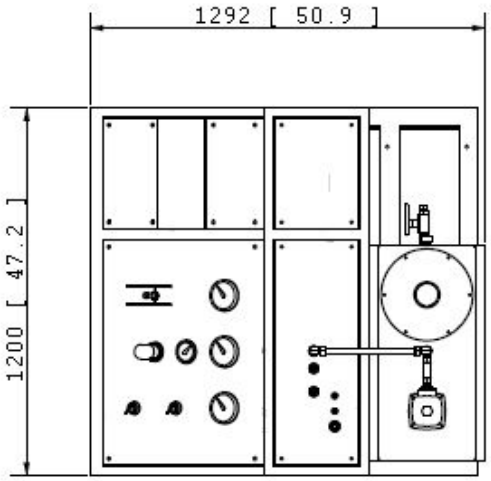
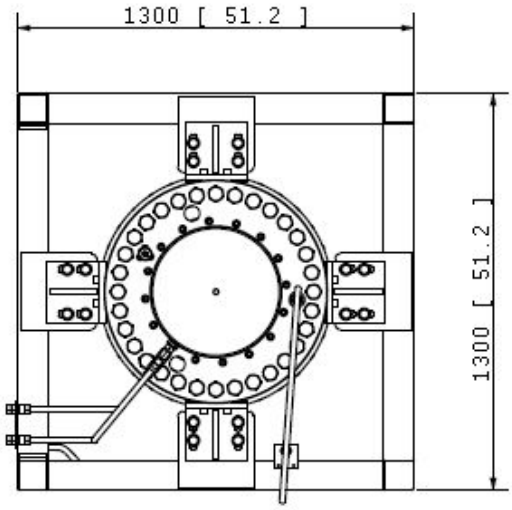
1.5. WEIGHT & DIMENSIONS

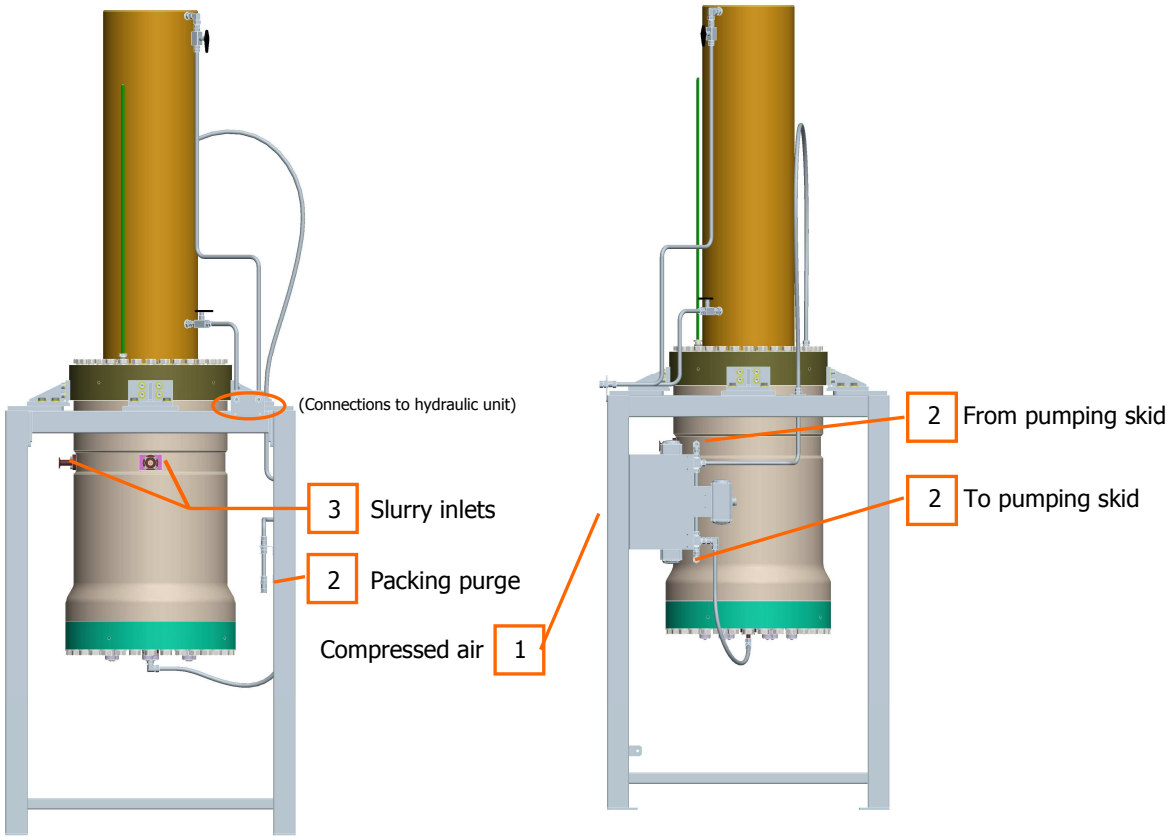
WEIGHT (approximated)
Column : 3500 kg Hydraulic unit : 470 kg Manipulating tools : 170 kg







1.6. CUSTOMER INTERFACES



LC590.700.VE100		
TYPE	**ITEM**	**DESCRIPTION**
Compressed Air	1	3/4" compression fitting from Swagelok®
From pumping skid (HIPERSEP) To pumping skid (HIPERSEP) Packing Purge	2	3/4" compression fitting from Swagelok®
Slurry Ports	3	1" Triclamp

The LC590 column is provided with the following :

- Two 3/4" OD flexible hoses for connection of the Piston and Flange to the Column packing valves
- One (1) set of column tools (wrenches) for assembly, packing/unpacking operations, and maintenance operations

1.7. REQUIRED UTILITIES

LC590.700.VE100				
TYPE	**QUALITY**	**CAPACITY**	**PRESSURE**	**TEMPERATURE**
Compressed Air	40 µm filtered, oil free, dry	5 Nm3/min (1)	6 barg	Room
Electricity	400V / 3 Ph / 50Hz	7.5 kW1)	NA	NA
Process	2 µm Filtered	2500 l/h max	100 barg max	5°C to 60 °C
Slurry	Not too viscous	9 m3/h max	0.5 barg max	Room
Thermostation	N/A	N/A	N/A	N/A

(1) During Packing operation otherwise negligible.

The hydraulic oil used is MOBIL DTE FM46, which is a clear oil, suitable for pharmaceutical and food applications.

2. STANDARDS & NORMS

LC590.700.VE100 EU Version:

As a pressure vessel, the LC590 is designed following the CODAP calculation code. It complies with the following EC directives:

- EC Machine Directive 2006/42/EC, May 17th 1998
- EC Pressure Vessel Directive 97/23/EC, 23rd of May 1997
- EC Directive for apparatus in explosive atmospheres 94/9/EC, 23rd of March 1994
- With the following ATEX marking II3G IIB T4 (IEC / CENELEC)

Optional pressure transmitter (NVS20924):

- EC Low Voltage Directive 2006/95/EC, December 15th 2004 including amendments
- EC Electro Magnetic Compatibility Directive 2004/108/EC, December 12th 2006 including amendments

LC590.700.VE100 US Version:

As a pressure vessel, the LC590 is designed following the ASME calculation code. It conforms to widely accepted industry standards and good manufacturing practices and is provided with U stamp.

Optional pressure transmitter (NVS20924):

- Rated for Class 1 Div 2 Group C&D (NEC500)

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3. SCOPE OF TESTING

The LC590 is fully tested during the Factory Acceptance Test (FAT) and the Site Acceptance Test (SAT)(1) in order to gather evidence that :

- The equipment has been manufactured following NOVASEP Process design documentation
- The manufactured equipment is operating within the specified tolerances

(1) : Only tests due to dismounting (for transportation purposes) or tests where the customer environment has an impact on the equipment setting are reproduced during SAT.

The applicable tests are mainly (but not limited to) the following:

- Check of the equipment against the engineering documents: P&ID, Mechanical Drawing, etc.,
- Check of the instrumentation (test or verify against calibration certificate if still valid),
- Check of the safety devices (emergency stops, relief valve, etc.),
- Check of the critical functions.

To get a fully detailed list of applicable tests, please refer to the FAT & SAT protocols of the LC590, which are available upon request.

4. DELIVERED DOCUMENTATION

4.1. ENGINEERING DOCUMENTATION

The following documentation is provided as an electronic copy (CD-Rom).

DISCIPLINE	ENGINEERING DOCUMENTATION
Process Detail Engineering	• Piping & Instrument Diagram (P&ID) • Process Parts List (PPL) • Interfaces Design Specifications (IDS) (Process, Mechanical)
Mechanical Detail Engineering	• General Drawing (including detail drawings nomenclature) • General tubing drawings (including item nomenclature)

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4.2. TECHNICAL DOCUMENTATION

The following documentation is provided as an electronic copy (CD-Rom).

DISCIPLINE	ENGINEERING DOCUMENTATION
General	• User Manual • Spare Parts List
Process	• Piping & Instrument Diagram (P&ID) • Process Parts List (PPL) • Interface Design Specifications (IDS) (Process, Mechanical) • Manufacturer technical documentation for process components • Material conformity certificates and FDA certificates of the components in contact with the process • Calibration certificates for process components
Mechanical	• General Drawing (including detail drawings nomenclature) • General tubing drawings (including item nomenclature) • Material conformity certificates and FDA certificates of the components in contact with the process • Column manufacturer book
Normative[(1)]	• Safety instruction • Incorporation declaration EC 97/23 (if applicable) • Incorporation declaration covering : o EC Machine Directive 2006/42/EC, May 17th 1998 o EC Pressure Vessel Directive 97/23/EC, 23rd of May 1997 o EC Directive for apparatus in explosive atmospheres 94/9/EC, 23rd of March 1994 o EC Low Voltage Directive 2006/95/EC, December 15th 2004 including amendments o EC Electro Magnetic Compatibility Directive 2004/108/EC, December 12th including amendments

[(1)] If this equipment is associated with another NOVASEP equipment like a pumping module, additional certificates will be provided.

4.3. TESTING DOCUMENTATION

The following documentation is provided as two binders :

- 1 binder **copy** of the FAT
- 1 binder **copy** of the SAT

DISCIPLINE	ENGINEERING DOCUMENTATION
FAT	• FAT Protocol, • FAT test procedures, • Test reports of each individual test performed during the FAT, • FAT report.
SAT	• SAT Protocol, • SAT test procedures, • Test reports of each individual test performed during the SAT, • SAT report.

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5. SPARE PARTS LIST (NVS20429)

LC590.700.VE100			
NVS CODE	Qty	DESCRIPTION	ITEM
NVS05500	2	SS316L mesh woven frit for piston (2 µm relative porosity & 5µm absolute porosity).	1
NVS05530	2	SS316L mesh woven frit for flange (2 µm relative porosity & 5µm absolute porosity).	1
NVS06635	2	PTFE guide seal	1
NVS06633	3	PTFE wiper seal	1
NVS06507	3	Spring loaded seal	1
NVS05509	3	FEP covered Silicon O-ring	1
NVS08483	3	FEP covered Silicon O-ring	1
NVS05481	3	FEP covered Silicon O-ring	1
NVS05526	3	FEP covered Silicon O-ring	1
NVS05533	3	FEP covered Silicon O-ring	1
NVS05504	3	FEP covered Silicon O-ring	1
NVS05497	3	FEP covered Silicon O-ring	1
NVS05426	3	FEP covered Silicon O-ring for slurry nozzle	1
NVS09489	1	100 L of hydraulic oil for column jack (DTE FM46)	11

Note :
This spare parts list is not included in the deliverables of a column. Indicated quantities are to be seen as a recommendation.

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6. HOW TO ORDER

To place an order please recall in your order the following NOVASEP's code :

DESCRIPTION	NOVASEP CODE
LC590.700.VE100 CODAP	NVS22701
LC590.700.VE100 ASME	N/A
SPARE PARTS	NVS20429
OPTIONAL PRESSURE TRANSMITTER	NVS20924
HANDLING TOOLS	NVS22857

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